

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:  
Jenny LOUIE-HELM et al.

Divisional of Serial No.: 10/014,750

Group Art Unit: Unassigned

Filing Date: Filed Herewith

Examiner: Unassigned

Title: FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE  
FORM USING IN VITRO DISINTEGRATION TEST DATA

**INFORMATION DISCLOSURE STATEMENT**

**Mail Stop Patent Application**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

The references identified below were disclosed and/or cited in parent application Serial No. 10/014,750, filed October 25, 2001, and, as such, copies thereof are not included pursuant to the provisions of 37 CFR § 1.98(d).

PTO-1449 forms listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
3,960,150	6/1/76	Hussain et al.
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,695,467	9/22/87	Uemura et al.
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Serial No. 10/066,146	Filed 2/1/02	Lim et al.
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Serial No. 10/280,309	Filed 10/25/02	Berner et al.
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SIEPMANN et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> <u>16</u> (11):1748-1756.
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This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As this Information Disclosure Statement is being filed concurrently with the application, no fee is required.

Respectfully submitted,

By:

A handwritten signature in cursive script, appearing to read "Karen Canaan", written over a horizontal line.

Karen Canaan  
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

**Complete if Known**

Sheet	1	of	4	Application Number	Divisional of 10/014,750
				Filing Date	Filed Herewith
				First Named Inventor	Jenny LOUIE-HELM et al.
				Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	3100-0003.10

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	AA	3,960,150	6/1/76	Hussain et al.			
	AB	4,434,153	2/28/84	Urquhart et al.			
	AC	4,690,824	9/1/87	Powell et al.			
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	AE	4,748,023	5/31/88	Tamás et al.			
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	AI	4,865,849	9/12/89	Conte et al.			
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	AN	5,213,808	5/25/93	Bar-Shalom et al.			
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	AR	5,425,950	6/20/95	Dandiker et al.			
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	AT	5,508,040	4/16/96	Chen			
	AU	5,549,913	8/27/96	Colombo et al.			
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	BG	5,783,212	7/21/98	Fassihi et al.			
	BH	5,811,126	9/22/98	Krishnamurthy			
	BI	5,827,984	10/27/98	Sinnreich et al.			
	BJ	5,837,379	11/17/98	Chen et al.			
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	BN	5,891,474	4/6/99	Busetti et al.			
	BO	5,897,874	4/27/99	Stevens et al.			
	BP	5,916,595	6/29/99	Chen et al.			
	BQ	5,945,125	8/31/99	Kim			

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 4

**Complete if Known**

Application Number	Divisional of 10/014,750
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First Named Inventor	Jenny LOUIE-HELM et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	3100-0003.10

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	BR	5,972,389	10/26/99	Shell et al.			
	BS	6,027,748	2/22/00	Conte et al.			
	BT	6,033,685	3/7/00	Qiu et al.			
	BU	6,066,337	5/23/00	Allen et al.			
	BV	6,093,420	7/25/00	Baichwal			
	BW	6,120,803	9/19/00	Wong et al.			
	BX	6,174,497	1/16/01	Roinestad et al.			
	BY	6,177,104	1/23/01	Allen et al.			
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	CB	6,221,395	4/24/01	Maggi et al.			
	CC	6,261,601	7/17/01	Talwar et al.			
	CD	6,340,475	01/22/02	Shell et al.			
	CE	6,368,628	4/9/02	Seth			
	CF	6,451,808	9/17/02	Cowles			
	CG	6,488,962	12/3/02	Berner et al.			
	CH	2001/0018070	8/30/01	Shell et al.			
	CI	Serial No. 09/425,491	10/22/99	Shell et al.			10/22/99
	CJ	Serial No. 10/029,134	10/25/01	Gusler et al.			10/25/01
	CK	Serial No. 10/045,823	11/6/01	Shell et al.			11/6/01
	CL	Serial No. 10/066,146	2/1/02	Lim et al.			2/1/02
	CM	Serial No. 10/152,914	5/20/02	Fara et al.			5/20/02
	CN	Serial No. 10/280,309	10/25/02	Berner et al.			10/25/02
	CO	Serial No. 10/280,852	10/25/02	Devane et al.			10/25/02

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	CR	GB 1330829	9/19/73	United Kingdom			
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	CT	WO 98/55107 A1	12/10/98	PCT			
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	CV	WO 00/38650 A1	7/6/00	PCT			
	CW	WO 01/32217 A3	5/10/01	PCT			
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	CY	WO 01/97783 A1	12/27/01	PCT			
	CZ	WO 02/083687 A1	10/24/02	PCT			

Examiner  
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Considered

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Sheet	3	of	4	Attorney Docket Number	3100-0003.10

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Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T	
	DA	ABRAHAMSSON et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.		
	DB	APICELLA et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.		
	DC	BAUMGARTNER et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric Residence Time," <i>International Journal of Pharmaceutics</i> 195:125-135.		
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	DL	JU et al. (1995), "Drug Release from Hydrophilic Matrices. 1. New Scaling Laws for Predicting Polymer and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> 84(12):1455-1463.		
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	DQ	LAPIDUS et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> 55(8):840-843.		
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	DX	SHAMEEM et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> 12(7):1049-1054.		
	DY	SIEPMANN et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.		
	DZ	YANG et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.